REMARKS

Interview

Applicants would like to thank the Examiner for her time in discussing the application over the phone. During the phone interview, the Examiner suggested amending the claims to recite specific hybridization conditions and functional language for the encoded protein.

Status of the Claims

Claims 72-78, and 80-92 are pending in the present application. Claims 1-71 and 79 have been canceled without prejudice or disclaimer of the subject matter claimed therein. New claims 88-92 have been added.

Amendments to the Claims

Claims 72, 73, and 80-87 have been amended and new claims 88-92 have been added to more clearly define the claimed invention. The amendments to the claims and the addition of new claims do not include prohibited new matter. Support for the amendments and the new claims are provided below.

Claim 72 has been amended as suggested by the Examiner. Support for the amendment can be found in paragraphs 0068, 0150-0153, and 0209.

Claims 73, 84, and 86 have been amended to correct inadvertent typographical errors.

Claims 80-82, 85, and 87 have been amended to correct the dependency.

Claim 83 has been amended as suggested by the Examiner.

Support for new claim 88 can be found in paragraphs 0009, 0152, and 0209.

Support for new claims 89-92 can be found in paragraphs 0068, 0071, 0076, and 0077.

Rejections of the Claims Under 35 U.S.C. § 112, First Paragraph

A. Claims 72, 73, and 78-87 are rejected under 35 U.S.C. § 112, first paragraph, purportedly because the specification is only enabling for an isolated nucleic acid molecule comprising SEQ ID NO: 1 encoding the amino acid sequence of SEQ ID NO: 2.

The Office Action alleges that the specification does not enable the breadth of the claims without undue experimentation. Moreover, the Office Action cites the *Wands* factors for consideration as to what is undue experimentation. Since Applicants addressed each of the

Wands factors in detail in the previous response of September 7, 2004, Applicant will focus on the specific issues raised by the Examiner in the current Office Action.

The Office Action alleges that there is insufficient guidance as to the "hybridization conditions" used by Applicant and that the state of the prior art is unpredictable as to hybridization of probes and to the structure/function of the protein encoded by the claimed nucleic acid.

Claim 72 has been amended to recite specific hybridization conditions and to include specific functional limitation for the proteins encoded by the claimed nucleic acids, and claim 79 has been canceled. Claim 72 requires that the encoded proteins not only are differentially expressed in mast cells activated through IgE receptor but also suppress the release of mediators from mast cells. Claim 72 as it stands includes both structural and functional limitations that are described and enabled by the specification. Claims 72 and its dependent claims 73-78 and 80-88 only encompass nucleic acid molecules that meet both of these limitations. The claims do not encompass an unlimited variety of nucleic acid molecules. It would not require undue experimentation for the skilled artisan to practice the claimed invention.

Moreover, the specification provides sufficient guidance and Examples for the scope of the claimed invention. The specification discloses SEQ ID NO: 2 and the nucleic acid encoding SEQ ID NO: 2. In the Examples, specifically Examples 1, 2, and 5, the specification discloses isolation and cloning of the MC1 clone comprising SEQ ID NO: 2. In Example 5, the specification teaches that the MC1 clone suppresses the release of various mediators, such as the lipid mediators LTC4 and PGD2 and the cytokine GM-CSF, from mast cells. The specification provides guidance for determining the functional property of the proteins encoded by the claimed nucleic acid molecules. Further, since the claims require that the nucleic acid hybridizes to the complement of the nucleic acid encoding SEQ ID NO: 2 and since SEQ ID NO: 2 encodes a protein having the functional limitation recited in the claims, the claims only encompass nucleic acids having the structural limitations recited in the claims and encoding proteins that meet the functional limitations of the claims. Accordingly, given the teachings provided by the specification, it would not require undue experimentation to obtain nucleic acids that hybridize to the complement of the nucleic acid encoding SEQ ID NO: 2 under the recited conditions and that encode a protein that is differentially expressed in activated mast cell.

Applicants respectfully point out that new claims 89 and 90 are directed to probes and primers that hybridize to the complement of the nucleic acid encoding SEQ ID NO: 2 under specific hybridization conditions. New claims 91 and 92 are directed to probes and primers comprising or consisting of specific sequences of SEQ ID NO: 1. This rejection is not relevant to new claims 89-92, since the specification provides sufficient guidance for the probes encompassed by the claims.

Applicants respectfully request withdrawal of the rejection.

B. Claims 72, 73, 78-87 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The Office Action alleges that there is inadequate written description regarding the structure/function of all the nucleic acid molecules that hybridize to the complement of the nucleic acid encoding SEQ ID NO: 2. As discussed above, claim 72 has been amended to recite specific hybridization conditions and to include specific functional limitation for the proteins encoded by the claimed nucleic acids, and claim 79 has been canceled. Claim 72 requires that the encoded proteins not only are differentially expressed in mast cells activated through IgE receptor but also suppress the release of mediators from mast cells. Claim 72 as it stands includes both structural and functional limitations that are described and enabled by the specification. Claims 72 and its dependent claims 73-78 and 80-88 only encompass nucleic acid molecules that meet both of these limitations. Accordingly, the nucleic acids encompassed by the claims are adequately described by the specification.

Regarding the Guidelines for Written Description Requirement, Applicants respectfully reiterates that Example 9 of the *Revised Interim Written Description Guidelines Training Materials* (1999) discloses a claim with hybridization language. The claim was found to be adequately described when the specification discloses a single species, SEQ ID NO: 1. The reason is that the claim sets forth the hybridization conditions, and one of skill in the art would not expect substantial variation among species encompassed within the scope of the claims. Likewise, claim 72 of the present application includes the limitation that the nucleic acid

molecules must hybridize under the specified conditions to the complement of a nucleic acid molecule encoding SEQ ID NO: 2 thereby limiting variation among the nucleic acid molecules encompassed within the scope of the claims.

Further, claim 72 requires that the proteins encoded by the nucleic acid molecules suppress the release of mediators from mast cells. Example 5 shows that MC1 suppresses the release of mediators from mast cells. The specification provides adequate written description for the structure/function of the claimed nucleic acids and their encoded proteins.

Accordingly, both the hybridization of nucleic acid molecules to the complement encoding SEQ ID No: 2 and the down regulation of the release of mediators from mast cells by the protein encoded by SEQ ID NO: 2, are described in the specification. Thus, claim 72 and its dependent claims, reciting both structural and functional limitations, do not lack written description.

Regarding the structure/function of nucleic acid molecules that hybridize to the complement of SEQ ID NO: 2, Applicants respectfully submit that the function of a nucleic acid as a probe or primer is to hybridize to structurally related nucleic acids for identification or isolation of related nucleic acid molecules, as described in the specification, especially in paragraphs 0076-0078. New claims 89-92 are directed to probes or primers. Claims 89 and 90 require that the claimed nucleic acid molecules hybridize to the complement of SEQ ID NO: 2 under the specified conditions, and claims 91 and 92 require that the nucleic acid molecules have a specific structure. Thus, the structural limitations recited in the claims and the function of the claimed probes and primers are adequately described by the specification.

Respectfully, the specification has adequately described the claimed invention and applicants request withdrawal of this rejection.

Rejections of the Claims Under 35 U.S.C. § 112, Second Paragraph

Claim 83, 84, and 86 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 83 has been rejected because the recitation of "A host cell" renders the claim indefinite. Applicants do not agree with the rejection because the claim is not indefinite. If the

claim is being rejected for lacking enablement for the full scope, then it should be rejected under § 112, first paragraph. Although Applicants do not agree with the rejection, the claim has been amended as suggested by the Examiner to overcome the rejection.

Claim 84 has been amended to recite "A host cell" and to correct an inadvertent grammatical error.

Claim 86 has been amended to correct an inadvertent grammatical error.

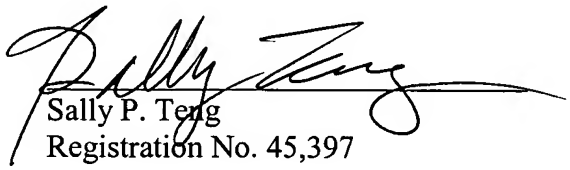
The amendments to the claims have overcome the rejection. Applicants respectfully request withdrawal of the rejection.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, they are invited to telephone the undersigned at their convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,
Morgan, Lewis & Bockius LLP



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